

Appendix G:
Appendix G-1:

Participant Safeguards
Safeguards Concerning Restraints and Restrictive Interventions

CMS Waiver	Answer (Highlights)	CMS Issue(s)	Possible Resolution/Further Consideration
a) Critical Event or Incident Reporting and Management Process. Indicate whether the State operates Critical Event or Incident Reporting and Management Process that enables the State to collect information on sentinel events occurring in the waiver program.	YES. The State operates a Critical Event or Incident Reporting and Management Process	None	
b) State Critical Event or Incident Reporting Requirements. Specify the types of critical events or incidents (including alleged abuse, neglect and exploitation) that the State requires to be reported for review and follow-up action by an appropriate authority, the individuals and/or entities that are required to report such events and incidents and the timelines for reporting. State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).	<p>Please see state definitions.</p> <p>DDD defines incidents as allegations or occurrences of abuse, neglect, and exploitation; events that cause harm to individual; events that serve as indicators of risk to participant health and welfare; and public complaints related to providers or participants. In addition, all "High" level incidents, including allegations of abuse and neglect, are required to be verbally reported to DDD staff immediately.</p> <p>Please see Reporting Requirements</p>	None	
c) Participant Training and Education. Describe how training and/or information is provided to participants (and/or families or legal representatives, as appropriate) concerning protections from abuse, neglect, and exploitation, including how participants (and/or families or legal representatives, as appropriate) can notify appropriate authorities or entities when the participant may have experienced abuse, neglect or exploitation.	Information concerning protections from abuse, neglect, and exploitation is provided to participants and their legal representative by Service Coordination, as well as in writing in the Non-Specialized Services Handbook.	None	
d) Responsibility for Review of and Response to Critical Events or Incidents. Specify the entity (or entities) that receives reports of critical events or incidents specified in item G-1-a, the methods that are employed to evaluate such reports, and the processes and time-frames for responding to critical events or incidents, including conducting investigations.	<p>The Division of Developmental Disabilities within DHHS, the State Medicaid agency, is responsible for overseeing the reporting of and response to critical incidents and events.</p> <p>Verbally reported to DDD staff immediately upon the provider becoming aware of the suspected abuse and neglect</p> <p>Reported in writing to the Department within 24 hours of the verbal report (web-based incident reporting system).</p>	None	
e) Responsibility for Oversight of Critical Incidents and Events. Identify the State agency (or agencies) responsible for overseeing the reporting of and response to critical incidents or events that affect waiver participants, how this oversight is conducted, and how frequently.	<p>A written summary must be submitted to the Department of the provider's investigation and action taken within 14 days (web-based incident reporting system).</p> <p>An aggregate report of incidents must be submitted to the Department on a quarterly basis. Each report must be received by the Department no later than 30 days after the last day of the previous quarter. The reports must include a compilation, analysis, interpretation of data, evidentiary examples to evaluate performance that result in a reduction in the number of incidents over time.</p>		

Appendix G:

Participant Safeguards

Appendix G-2:

The use of restraints is permitted during the course of the delivery of waiver services

CMS Waiver	Answer (Highlights)	CMS Issue(s)	Possible Resolution/Further Consideration
a) i. Safeguards Concerning the Use of Restraints. Specify the safeguards that the State has established concerning the use of each type of restraint (i.e., personal restraints, drugs used as restraints, mechanical restraints). State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).	<p>Please see state definitions.</p> <p>Use of mechanical restraints, physical restraints, seclusion, and aversive stimuli are not allowable habilitation techniques.</p> <p>Physical restraint or separation from harmful circumstances or from individuals at risk can only be used as an emergency safety intervention when the person must be kept from harm.</p> <p>Restrictive methods used should not be employed as punishment.</p> <p>In an emergency safety intervention, may use separation - hands-on guidance away from harm or to another area or room to safely protect the persons and others from immediate jeopardy or physical harm until the risk of harm is no longer present.</p> <p>The use of chemical restraints must be prescribed by a physician.</p>	None	
a) ii. State Oversight Responsibility. Specify the State agency (or agencies) responsible for overseeing the use of restraints and ensuring that State safeguards concerning their use are followed and how such oversight is conducted and its frequency:	<p>DHHS DDD is responsible for overseeing the use of restraints and ensuring that the state's safeguards are followed.</p> <p>The methods for detecting the unauthorized use, over use or inappropriate/ineffective use of emergency physical restraints or separation, and behavior modifying drugs and ensuring that all applicable state requirements is performed by state staff and are as follows:</p> <ol style="list-style-type: none"> 1) Review of each DD provider's policies and procedures during the provider enrollment process, with recommendations for change as applicable; 2) On-site certification review activities; 3) Review of critical incident reports; 4) Review of reports of events; 5) DDD Service Coordination monitoring 6) Complaint investigations. <p>An aggregate report of the incidents, prepared by each provider agency, is forwarded to the QIC on a quarterly basis. A summary of certification activities is completed by a DDD Program Specialist and is reviewed semi-annually by the DDD QI Committee (QIC).</p>	<p>The state may wish to clarify detection of unauthorized restraint outside of the monitoring and oversight process described in G-2-a-ii.</p> <p>Please clarify whether the use of mechanical restraints, physical restraints, seclusion, and aversive stimuli are/are not allowable (see 1st sentence in second paragraph). CMS is unclear whether these methods are or are not allowable since the State describes use the use of these methods which appear to be allowable in some circumstances.</p> <p>What documentation is used to track utilization of restraints consistent with a PCP or when an unexpected safety issue arises prior to development of a revised plan for the individual?</p> <p>The state may wish to remove references to restraints in this section as it repetitive with G-2-b. Are there other restrictive interventions beyond separation utilized by the state?</p> <p>Are there other restrictive interventions beyond separation utilized by the state? More detail is needed to support other restrictive interventions.</p>	

<p>b) i. Safeguards Concerning the Use of Restrictive Interventions. Specify the safeguards that the State has in effect concerning the use of interventions that restrict participant movement, participant access to other individuals, locations or activities, restrict participant rights or employ aversive methods (not including restraints or seclusion) to modify behavior. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency.</p>	<p>Please see Reporting Requirements (restrictive interventions section).</p> <p>Use of mechanical restraints, physical restraints, seclusion, and aversive stimuli are not allowable habilitation techniques.</p> <p>Physical restraint or separation from harmful circumstances or from individuals at risk can only be used as an emergency safety intervention when the person must be kept from harm.</p> <p>Restrictive methods used should not be employed as punishment.</p> <p>In an emergency safety intervention, may use separation - hands-on guidance away from harm or to another area or room to safely protect the persons and others from immediate jeopardy or physical harm until the risk of harm is no longer present.</p> <p>The use of chemical restraints must be prescribed by a physician.</p>	None	None
<p>b) ii. State Oversight Responsibility. Specify the State agency (or agencies) responsible for monitoring and overseeing the use of restrictive interventions and how this oversight is conducted and its frequency</p>	<p>DHHS DDD is responsible for overseeing the use of restraints and ensuring that the state's safeguards are followed.</p> <p>The methods for detecting the unauthorized use, over use or inappropriate/ineffective use of emergency physical restraints or separation, and behavior modifying drugs and ensuring that all applicable state requirements is performed by state staff and are as follows:</p> <ol style="list-style-type: none"> 1) Review of each DD provider's policies and procedures during the provider enrollment process, with recommendations for change as applicable; 2) On-site certification review activities; 3) Review of critical incident reports; 4) Review of reports of events; 5) DDD Service Coordination monitoring 6) Complaint investigations. <p>An aggregate report of the incidents, prepared by each provider agency, is forwarded to the QIC on a quarterly basis. A summary of certification activities is completed by a DDD Program Specialist and is reviewed semi-annually by the DDD QI Committee (QIC).</p>	None	
<p>b) i. Safeguards Concerning the Use of Restrictive Interventions. Specify the safeguards that the State has in effect concerning the use of interventions that restrict participant movement, participant access to other individuals, locations or activities, restrict participant rights or employ aversive methods (not including restraints or seclusion) to modify behavior. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency.</p>	<p>Please see Reporting Requirements (restrictive interventions section).</p> <p>Use of mechanical restraints, physical restraints, seclusion, and aversive stimuli are not allowable habilitation techniques.</p> <p>Physical restraint or separation from harmful circumstances or from individuals at risk can only be used as an emergency safety intervention when the person must be kept from harm.</p> <p>Restrictive methods used should not be employed as punishment.</p> <p>In an emergency safety intervention, may use separation - hands-on guidance away from harm or to another area or room to safely protect the persons and others from immediate jeopardy or physical harm until the risk of harm is no longer present.</p> <p>The use of chemical restraints must be prescribed by a physician.</p>	None	

<p>c) The State does not permit or prohibits the use of seclusion. Specify the State agency (or agencies) responsible for detecting the unauthorized use of seclusion and how this oversight is conducted and its frequency:</p>	<p>The methods for detecting the use of seclusion are as follows:</p> <ol style="list-style-type: none"> 1) Review of each DD provider's policies and procedures during the provider enrollment process, with recommendations for change as applicable; 2) On-site certification review activities; 3) Review of critical incident reports; 4) Review of reports of events; 5) DDD Service Coordination monitoring 6) Complaint investigations. <p>An aggregate report of the incidents, prepared by each provider agency, is forwarded to the QIC on a quarterly basis. A summary of certification activities is completed by a DDD Program Specialist and is reviewed semi-annually by the DDD QI Committee (QIC).</p>	<p>None</p>	
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Appendix G:
Appendix G-3:

Participant Safeguards
Medication Management and Administration

CMS Waiver	Answer (Highlights)	CMS Issue(s)	Possible Resolution/Further Consideration
a) Applicability	Yes. This Appendix applies	None	
b. Medication Management and Follow-Up	1) Medical professionals that prescribe the medications - medical professionals who prescribe them, the pharmacist who fills the prescriptions, and the provider's review committee.	None	None
i. Responsibility. Specify the entity (or entities) that have ongoing responsibility for monitoring participant medication regimens, the methods for conducting monitoring, and the frequency of monitoring.	2) Licensed health care professionals (typically an RN) whose scope of practice allows delegation of medication administration (typically medication aides).		
	3) DD Provider Agencies. The agency shall have a review committee committee to provide prior review of psychotropic medications used solely for the purpose of modifying behaviors which includes:		
	a. Persons qualified to evaluate behavioral research studies/proposals and the technical adequacy of proposed positive behavioral support plans; and		
	b. A physician, pharmacist, or other professional qualified to evaluate proposals for the use of medications to modify behavior.		
	4) Compliance reviews of the provider are completed by the Division of Public Health (DPH) within DHHS.		
b. Medication Management and Follow-Up	DPH is responsible for the oversight of compliance	None	None
ii. Methods of State Oversight and Follow-Up. Describe: (a) the method(s) that the State uses to ensure that participant medications are managed appropriately, including: (a) the identification of potentially harmful practices (e.g., the concurrent use of contraindicated medications); (b) the method(s) for following up on potentially harmful practices; and, (c) the State agency (or agencies) that is responsible for follow-up and oversight.	Oversight activities regarding the administration of behavior modifying medications:		
	a. Review of each DD provider's policies and procedures during the provider initial certification process;		
	b. On-site certification review activities; and		
	c. DDD Service Coordination monitoring.		
c. Medication Administration by Waiver Providers	Waiver providers are responsible for the administration of medications to waiver participants who cannot self-administer and/or have responsibility to oversee participant self-administration of medications.	None	
i. Provider Administration of Medications.			
c. Medication Administration by Waiver Providers	DD provider agencies have ongoing responsibility to ensure medications administered by the provider are monitored and are being provided in accordance with the Medication Aide Act . Medication aides are defined as:	None	
ii. State Policy. Summarize the State policies that apply to the administration of medications by waiver providers or waiver provider responsibilities when participants self-administer medications, including (if applicable) policies concerning medication administration by non-medical waiver provider personnel. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).	1) a licensed health care professional whose scope of practice allows medication administration		
	2) a recipient with capability and capacity to make informed decision about medications for his/her medication (i.e. self-administration)		
	3) a caretaker - a parent, foster parent, family member, friend, or legal guardian who provides care for an individual.		
	Individuals may self administer if they are 19 years or older and physically capable by evaluation of the DD provider agency.		
c. Medication Administration by Waiver Providers	Medication errors must be reported to the person responsible for providing directions and monitoring.	Please confirm what state agencies are authorized to request medication error reports and how this information is tracked and addressed by the SMA or OA.	
iii. Medication Error Reporting. Providers responsible for medication administration are required to record medication errors but make information about medication errors available only when requested by the State.	Medication errors are any violation of the "Five Rights" - 1) providing the right medication, 2) to the right person, 3) at the right time, 4) in the right dose, and 5) by the right route		
Specify the types of medication errors that providers are required to record:			

<p>c. Medication Administration by Waiver Providers</p> <p>iv. State Oversight Responsibility. Specify the State agency (or agencies) responsible for monitoring the performance of waiver providers in the administration of medications to waiver participants and how monitoring is performed and its frequency.</p>	<p>Each DD provider agency must have policies and procedures for internal quality assurance and quality improvement. The provider's QA/QI activities include reviewing medication errors to identify potentially harmful practices, and follow up to prevent errors in the administration of medications, such as retraining med aides or disciplinary action.</p> <p>DDD completes the following oversight activities regarding the administration of behavior modifying medications:</p> <ul style="list-style-type: none"> a. Review and approval of each DD provider's policies and procedures during the provider initial certification process; b. On-site certification review activities; and c. DDD Service Coordination monitoring. 	None	
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Oversight: The Division of Developmental Disabilities within DHHS, the State Medicaid agency, is responsible for overseeing the reporting of and response to critical incidents and events.

State Critical Event or Incident Reporting Requirements

At a minimum the following incidents must be reported immediately upon provider, participant, or family becoming aware of the incident:

- 1) Allegation of abuse or neglect.
- 2) Allegation of financial exploitation.
- 3) Allegation of sexual exploitation.
- 4) Injuries to individuals which require medical attention and treatment by physician.
- 5) Injuries to individuals involving emergency safety interventions.
- 6) Discovery of injury of unknown origin.
- 7) Injuries or displacement to individual as a result of fire.
- 8) Medication error resulting in injury, serious illness, or hospitalization.
- 9) Use of an emergency safety intervention.
- 10) Use of physical, chemical, or mechanical restraint.
- 11) Deaths of persons served.
- 12) Injuries which require medical attention to others, resulting from behaviors of individual.
- 13) An individual served leaving supervision where the safety of the individual or others is potentially threatened.
- 14) Emergency Room, Hospitalization, or use of urgent care facilities regardless of type of injury.
- 15) Hospital admission due to mental health/behavioral concerns.
- 16) Any unplanned hospitalization or ER visit, or any unplanned use of urgent care facility.
- 17) Law enforcement contacts due to the behavior of an individual served.
- 18) Possible criminal activity by individual receiving services or staff person suspected of engaging in criminal activity towards an individual.
- 19) Attempted elopement but staff is present and/or behavior de-escalation occurs before elopement.
- 20) PRN psychotropic medication use.
- 21) Property damage caused by individual.
- 22) Seizure that last over five minutes or over the timeframe set by the individual's physician, or result in treatment at an ER or hospital.

Provider Timelines for Critical Event or Incident Reporting Requirements

- 1) Verbally reported to DDD staff immediately upon the provider becoming aware of the suspected abuse and neglect
- 2) Reported in writing to the Department within 24 hours of the verbal report (web-based incident reporting system).
- 3) A written summary must be submitted to the Department of the provider's investigation and action taken within 14 days (web-based incident reporting system).
- 4) An aggregate report of incidents must be submitted to the Department on a quarterly basis. Each report must be received by the Department no later than 30 days after the last day of the previous quarter. The reports must include a compilation, analysis, interpretation of data, evidentiary examples to evaluate performance that result in a reduction in the number of incidents over time.

The following documentation is required when restrictive interventions are used:

- 1) Written agency provider policies and procedures;

2) Written positive support plan to be used in conjunction with the restrictive measure, the criterion for the elimination of the restrictive measure, and method to collect data;
3) Written discussion and prior approval by the service plan team and documentation the service plan team's determination of the individual's ability to acquire, retain, or understand the information proposed in the restrictive measure;
4) Written informed consent;
5) Incident reports related to the use of restrictive interventions; and
6) Orientation, training, and/or competency standards for staff prior to implementation of restrictive measures.

State Critical Submitted Definitions

Exploitation - the taking of property of a vulnerable adult by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Restraint - any physical hold, device, or chemical substance that restricts, or is meant to restrict, the movement or normal functioning of an individual. Includes medication used solely to control or alter behavior, physical intervention, or mechanical device used to restrict the movement, normal function of a portion of the person's body or control the behavior of a person receiving services. Devices used to provide support for the achievement of functional body position or proper balance, and devices used for specific medical and surgical (as distinguished from

Chemical restraints - drugs, or psychotropic medications used solely for the purpose of modifying behaviors may be used only with the consent of the individual or legal PRN psychotropic medications are prohibited

Devices used to provide support for the achievement of functional body position or proper balance, and devices used for specific medical and surgical (as distinguished from behavioral) treatment are excluded as a restraint.

Emergency safety intervention - the use of physical restraint or separation as an immediate response to an emergency safety situation. Separation is not the same as seclusion which is defined as “involuntary confinement or detainment alone in a room or area where the individual is physically prevented from leaving or having contact with others.” Seclusion is prohibited.

Psychotropic Medication - any medication prescribed specifically to treat mental illness and associated symptoms. The major classes of psychotropic medication are antipsychotic (neuroleptic), antidepressant, antianxiety, antimania, stimulant, and sedative or hypnotic. Other miscellaneous medications are considered to be a psychotropic medication when they are specifically prescribed to treat a mental illness.

Physical injury - harm, pain, illness, impairment of physical function, or damage to body tissue.

Seclusion - the involuntary confinement of an individual alone in a room or an area from which the individual is physically prevented from having contact with others or leaving.